

ASSEMBLY BILL

No. 2077

Introduced by Assembly Member Solorio

February 18, 2010

An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, as introduced, Solorio. Centralized hospital packaging pharmacies.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. A knowing violation of the Pharmacy Law is a crime.

This bill would authorize a centralized hospital packaging pharmacy, as defined, to prepare medications, by performing specified functions, for administration only to patients within its own general acute care hospital and one or more general other acute care hospitals if the hospitals are under common ownership, in California, and within a 100 mile radius of the pharmacy. The bill would prohibit a person from

conducting a centralized hospital packaging pharmacy without a specialty license from the board and would require applicants to apply annually to the board on forms developed by the board. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.

The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that drugs prepared in advance of receipt of a patient specific prescription shall meet specified standards, that medications be barcoded to be readable at the patient's bedside, and that medication labels contain specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4029 of the Business and Professions
- 2 Code is amended to read:
- 3 4029. (a) "Hospital pharmacy" means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets
- 8 all of the requirements of this chapter and the rules and regulations
- 9 of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, *except as provided in Article 7.6 (commencing with Section 4128)*. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this ~~paragraph~~ *subdivision* shall be construed to restrict or expand the services that a hospital pharmacy may provide.

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Centralized Hospital Packaging Pharmacies

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to patients within its own general acute care hospital and one or more other general acute care hospitals if the hospitals are (1) under common ownership, (2) in California, and (3) located within a 100 mile radius of the centralized hospital packaging pharmacy.

(1) Preparing unit dose packages for single administration to patients from bulk containers, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(2) Preparing compounded unit dose drugs for parenteral therapy for administration to patients, if each compounded unit dose drug is barcoded to contain at least the information required by Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to patients, if each unit dose package is barcoded to contain at least the information required by Section 4128.4.

(b) For the purposes of this article, a "centralized hospital packaging pharmacy" means a licensed hospital pharmacy located within a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

1 4128.1. (a) No person shall conduct a centralized hospital
2 packaging pharmacy unless it has obtained a specialty license from
3 the board.

4 (b) A licensed hospital pharmacy serving only its own patients
5 shall not be required to obtain a specialty license as described in
6 subdivision (a).

7 4128.2. (a) In addition to the pharmacy license requirement
8 described in Section 4110, a centralized hospital packaging
9 pharmacy shall obtain a specialty license from the board prior to
10 engaging in the functions described in Section 4128.

11 (b) An applicant seeking a specialty license pursuant to this
12 article shall apply to the board on forms established by the board.

13 (c) Before issuing the specialty license, the board shall inspect
14 the pharmacy and ensure that the pharmacy is in compliance with
15 this article and regulations established by the board.

16 (d) A license to perform the functions described in Section 4128
17 may only be issued to a pharmacy that is licensed by the board as
18 a hospital pharmacy.

19 (e) A license issued pursuant to this article shall be renewed
20 annually and is not transferrable.

21 (f) An applicant seeking renewal of a specialty license shall
22 apply to the board on forms established by the board.

23 (g) A license to perform the functions described in Section 4128
24 shall not be renewed until the pharmacy has been inspected by the
25 board and found to be in compliance with this article and
26 regulations established by the board.

27 (h) The fee for issuance or annual renewal of a centralized
28 hospital packaging pharmacy license shall be six hundred dollars
29 (\$600) and may be increased by the board to eight hundred dollars
30 (\$800).

31 4128.3. A centralized hospital packaging pharmacy may prepare
32 and store a limited quantity of the unit dose drugs authorized by
33 Section 4128 in advance of receipt of a patient specific prescription
34 in a quantity as is necessary to ensure continuity of care for an
35 identified population of patients of the general acute care hospital
36 based on a documented history of prescriptions for that patient
37 population. The expiration date for these drugs shall meet
38 established compendium standards as stated in the United States
39 Pharmacopiea and other widely accepted references.

1 4128.4. Any unit dose medication produced by a centralized
2 hospital packaging pharmacy shall be barcoded to be readable at
3 the patient's bedside. The bar code shall contain at least the
4 following information:

- 5 (a) Expiration date.
- 6 (b) Lot number or control number.
- 7 (c) National Drug Code Directory number.

8 4128.5. The label for each unit dose medication produced by
9 a centralized hospital packaging pharmacy shall contain all of the
10 following information:

- 11 (a) Expiration date.
- 12 (b) Established name of the drug.
- 13 (c) Quantity of the active ingredient.
- 14 (d) Special storage or handling requirements.
- 15 (e) Name of the packaging pharmacy.

16 4128.6. All compounding and packaging functions specified
17 in Section 4128 shall be performed only in the licensed centralized
18 hospital packaging pharmacy and that pharmacy shall comply with
19 all applicable regulations, including, but not limited to, regulations
20 regarding compounding and when appropriate, sterile injectable
21 compounding.

22 4128.7. A centralized hospital packaging pharmacy and the
23 pharmacists working in the pharmacy shall be responsible for the
24 integrity, potency, quality, and labeled strength of any unit dose
25 drug product prepared by the centralized hospital packaging
26 pharmacy.

27 SEC. 3. No reimbursement is required by this act pursuant to
28 Section 6 of Article XIII B of the California Constitution because
29 the only costs that may be incurred by a local agency or school
30 district will be incurred because this act creates a new crime or
31 infraction, eliminates a crime or infraction, or changes the penalty
32 for a crime or infraction, within the meaning of Section 17556 of
33 the Government Code, or changes the definition of a crime within
34 the meaning of Section 6 of Article XIII B of the California
35 Constitution.